

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

December 22, 2001

Submitted By: NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED High Pressure PTA Catheter; Unclassified

Predicate Devices: NuMED Ghost II PTA Catheter

Device Description: The NuMED, Inc. High Pressure PTA catheter is a coaxial catheter for use in PTA applications. It is available in varied sizes depending on which catheter that you need. The available sizes are below. One lumen permits guidewire insertion to facilitate advancement of the catheter, while the other lumen is for balloon inflation and deflation. The balloon of the High Pressure PTA is made of a non-compliant polyethylene. It has an increased wall thickness that allows the balloon to achieve a higher pressure before rupture occurs. The balloon is designed to inflate to a specific diameter at a given pressure. The change in diameter is minimal over the range of inflation pressures. The catheter features a proximal end bifurcate with two distinct luminal passages. The balloon extension is marked with the product lot number and the balloon size. The outer body and inner body tubing is made of Pebax. The area under the balloon is enhanced with either one or two radiopaque platinum image bands depending on the model. If marked with one image band, it is centered under the midpoint of the balloon. If it is marked with two image bands, they are located under the shoulders of the balloon. The catheter is packaged in a polyethylene loop and is double packed in two heat sealed Tyvek pouches. The High Pressure catheter is available in standard diameters from 4mm to 10mm in standard lengths of 2cm to 10cm.

Biocompatibility Testing:

The materials used in the NuMED High Pressure PTA Catheter is the same as those used in our other PTV Catheters (510(k) #K991977) which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.

Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc.

Intended Use: This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

**SPECIAL 510(k) - CONFIDENTIAL
HIGH PRESSURE PTA CATHETERS**

Comparison Information:

MODEL:	NUMED GHOST II PTA	NUMED HIGH PRESSURE PTA
Indications:	This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. These catheters are not designed to be used in the coronary arteries.	This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. These catheters are not designed to be used in the coronary arteries.
Introducer:	5.0Fr – 8.0Fr	6.0Fr – 8.0Fr
Shaft Size:	5.0Fr	5.0Fr – 6.0Fr
Guidewire Size:	0.035"	0.035"
Usable Length:	40cm, 75cm, 120cm, 150cm	40cm, 75cm, 120cm,
Balloon Diameter:	3mm – 10mm, 12mm	4mm – 10mm
Balloon Length:	1.5cm – 10cm	2cm – 10cm
Materials:	Shaft: PES2 Balloon: PES2 Image Band: Platinum	Shaft: Pebax Balloon: PES2 Image Band: Platinum
Construction:	Dual Lumen construction with distally mounted non-compliant balloon.	Coaxial construction with distally mounted non-compliant balloon.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2001

Ms. Nichelle R. Laflesh
Numed, Inc.
2880 Main St.
Hopkinton, NY 12965

Re: K010880
Trade Name: Numed High Pressure PTA Catheters
Regulatory Class: II (two)
Product Code: DQY & LIT
Dated: April 6, 2001
Received: April 9, 2001

Dear Ms. LaFlesh:

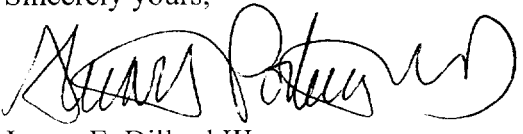
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for 

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K 010880

Device Name: **NuMED High Pressure PTA Catheter**

Indications For Use:

- This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐

(Optional Format 1-2-96)

 4-20-1
Division of Cardiovascular & Respiratory Devices
510(k) Number K010880